

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE LITIGATION

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) MDL No. 1456  
)

) Civil Action No. 01-CV-12257 PBS  
)

THIS DOCUMENT RELATES TO  
01-CV-12257-PBS AND 01-CV-339

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) Judge Patti B. Saris  
) Chief Magistrate Judge Marianne B. Bowler  
)

**THE BMS DEFENDANTS' REPLY MEMORANDUM OF LAW IN  
SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT**

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Dated: April 28, 2006

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Preliminary Statement

Plaintiffs' Memorandum in Opposition to the BMS Defendants' Motion for Summary Judgment ("Pltfs.' Opp.") is replete with distortions, mischaracterizations and unsubstantiated statements. That is because plaintiffs are unable to dispute the essential facts on which BMS bases its motion. Plaintiffs do not even provide a proper statement pursuant to Local Rule 56.1, which in and of itself is grounds for deeming BMS's facts admitted.<sup>1</sup>

In any event, plaintiffs have not raised any genuine issue with respect to the following facts:<sup>2</sup>

1. For the drugs at issue in this case, BMS's list prices are the actual prices that appear on invoices to wholesalers and are the prices at which BMS achieves the overwhelming proportion of its revenue.<sup>3</sup>
2. BMS reports list prices, not AWP, to industry publications, and BMS does not control the calculation or dissemination of AWP by those publications.<sup>4</sup>
3. "[T]he spread between list price and AWP was known to the government in various ways and assumed by the Medicare reimbursement system."<sup>5</sup>

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<sup>1</sup> Local Rule 56.1 requires "a concise statement of the material facts of record as to which it is contended that there exists a genuine issue to be tried, with page references to affidavits, depositions and other documentation." Plaintiffs' Rule 56.1 statement does not contain any citations to the record. Under the Rule, that alone is grounds for deeming BMS's facts admitted.

<sup>2</sup> By articulating the undisputed facts differently in this memorandum, BMS does not intend to suggest that its previous statements of undisputed facts are incorrect. This statement of undisputed facts is designed to reflect the evolution of the issues in the parties' briefing.

<sup>3</sup> Szabo Decl. ¶¶ 2-3, 11-12; Bell BMS Decl. ¶¶ 7a, 21, 24. (Abbreviations are those used in previous briefs.)

<sup>4</sup> Kaszuba Aff. ¶ 2; Szabo Decl. ¶ 5; Szabo Dep. Tr. 133, 135-36, 151, annexed to Edwards Decl. as Exh. B; Kaszuba Dep. Tr. 97-101, annexed to Edwards Decl. as Exh. C; Morgan Dep. Tr. 227, 230, annexed to Edwards Decl. as Exh. D.; Morgan Dep. Exhs. 4, 7, 56, annexed to Tretter Decl. as Exhs. 2-4; Morgan Dep. Exh. 41, annexed to Edwards Decl. as Exh. F; various BMS documents annexed to Edwards Decl. as Exh. E; Declaration of Steve W. Berman in Opposition to BMS's Motion for Summary Judgment Exhs. ("PXs") 21, 23, 30.

<sup>5</sup> Gov't Mem. in United States v. MacKenzie at 1, annexed to Edwards Decl. as Exh. I.

4. The government knew the spreads of certain BMS drugs at issue and nevertheless continued to use AWP as a reimbursement benchmark.<sup>6</sup>

The real issues on this motion are legal issues, which should be resolved now:

1. Are BMS's list prices unfair or deceptive? The answer to that is clearly no. There is no legal requirement that list prices reflect discounts.

2. Did BMS engage in unfair or deceptive acts by submitting its list prices to industry publications? The answer to that is clearly no. The government was not deceived by the mark-up of BMS's list prices by 20% or 25% to calculate AWP's; and, in any event, BMS is not responsible for the acts of third party publications that it does not endorse or control.

3. Is it unfair or deceptive to provide customers with truthful information about the financial consequences of their transactions? The answer to that is clearly no. In addition to being completely benign, such conduct could not have had any impact on the prices plaintiffs paid for drugs.

4. Could Medicare have been deceived by "mega spreads" if it knew about them? The question answers itself. There can be no deception where the person allegedly deceived knew the truth.

Plaintiffs' entire case is built on a foundation of rhetoric and demagoguery. BMS is not TAP; it has not violated any federal statutes; and its conduct is very different from what TAP admitted to in its guilty plea. BMS stands accused of doing nothing more than taking a standard approach to setting list prices and reporting them to industry publications so its drugs

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<sup>6</sup> OIG Report on Physicians' Cost for Chemotherapy Drugs (Nov. 1992); Ven-A-Care to Vladeck, Oct. 2, 1996, annexed to Edwards' Decl. as Exhs. L and M.

could be sold; if it had not done so, no one would have been able to obtain BMS's life-saving drugs.

### Statement of Facts

Instead of providing the Court with a coherent statement of facts, plaintiffs present a confusing array of immaterial and unsubstantiated assertions, most of which are distortions or mischaracterizations of the actual facts. Plaintiffs purport to summarize their view of the facts on pages 11 and 12 of their memorandum, referring to (a) "BMS's deliberate decision to report pricing information"; (b) "BMS's deliberate decision to . . . itself become a publisher of AWP's"; and (c) "its thorough awareness of how AWP's were derived from its prices" such that "AWP was a BMS-controlled fiction . . . ." (Pltfs.' Opp. at 11-12.) These assertions are completely misleading.

With respect to the assertion that BMS made a "deliberate decision" to report pricing information, plaintiffs ignore the undisputed fact that payors will not reimburse for drugs that are not listed in the publications. As reflected in the deposition of BMS's Diane Ihling:

"Pricing Support is responsible for providing product and pricing information to the three data services. If product is not added, the following occurs . . . . Reimbursement of drug cost by insurance companies directly or through third-party payors is denied without production information and AWP."

(Ihling Dep. Tr. 124-25, annexed to Tretter Decl. as Exh. 5.) Similarly, Denise Kaszuba testified that if BMS simply refused to send anything to the publications, "[t]hose products would not be eligible for prescribers." (Kaszuba Dep. Tr. 222, annexed to Tretter Decl. as Exh. 1.)

With respect to the claim that BMS "itself" published AWP's, plaintiffs fail to disclose that all of their proof in support of that proposition concerns communications between BMS and providers, not payors. (Plaintiffs' BMS Exhibits ("PXs") 24-27, 58.) There is no allegation, much less proof, that BMS communicated AWP's to class members, and it is

undisputed that payors, including Medicare, consulted the publications, not BMS, to determine AWP. (Tretter Decl. Exhs. 7-8.) Furthermore, if any payor had consulted OTN's AWP Price Report or Purchase History Report, they would have been able to determine the net sales prices as well as the AWP and therefore, even under plaintiffs' theory, could not have been deceived. (See PXs 27, 58.)

With respect to the claim that BMS "controlled" AWP, document after document, relied on by plaintiffs, demonstrates that this is not true. Thus, an April 2002 presentation on average wholesale price states that "AWP is outside of the control of BMS . . . ." (PX 21 at 9782.) Another presentation entitled "Sources of Price Data and their relationship to BMS pricing activities" states: "AWP is not determined or set by BMS . . . ." (PX 23 at 8211.) Another document entitled "Understanding AWP" states that mark-up factors "are set wholly at the discretion of the data services" and "AWPs are outside of the control of BMS . . . ." (PX 30 at 2095, 2097.) In addition to the other evidence, cited by BMS, demonstrating that it does not control AWP,<sup>7</sup> none of which is disputed by plaintiffs, the record demonstrates that there is no evidence supporting plaintiffs' claim that BMS controls AWP.

Many of plaintiffs other factual assertions are distorted or misleading. Thus:

- Plaintiffs assert that BMS "instructed" the publications to use a 25% mark-up factor for BMS oncology products. (Pltfs.' Opp. at 2.) BMS made such a request only one time, in 1992, and two of the publishers rejected it, demonstrating BMS does not control AWP.<sup>8</sup>
- Plaintiffs assert that BMS "reviewed the AWP for reasonability". (Pltfs.' Opp. at 2.) The document referred to in that testimony makes clear that "reasonability" meant whether the mathematical computation was correct (PX 10 at 108), and the witness testified that she had never suggested any change to a publication to correct anything other than typos. (Kaszuba Dep. Tr. 209-10, annexed to Tretter Decl. as Exh. 1.)

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<sup>7</sup> See footnote 4, *supra*.

<sup>8</sup> Kaszuba Aff. ¶¶ 3-4.

- Plaintiffs assert that “BMS knew that its AWP’s were fictitious.” (Pltfs.’ Opp. at 4.) The documents they rely on, however, explain that “[t]hrough the 1970s most wholesalers did charge the AWP”; “FirstDatabank has maintained the 20%-25% AWP markup legacy”; and “payors . . . know that AWP is artificially inflated”. (PXs. 28 at 9291; PX. 29 at 7211.)<sup>9</sup>
- Plaintiffs assert that BMS suggested lowering Vepesid’s AWP in order to create sales for Etopophos. (Pltfs.’ Opp. at 8.) Plaintiffs’ own expert has admitted that this did not happen. (Rosenthal Dep. Tr. 376-84, annexed to Tretter Decl. as Exh. 10.)

Plaintiffs also rely on numerous documents concerning self-administered drugs marketed by BMS’s Apothecan subsidiary. (See PXs 19, 20, 22, 39.) As plaintiffs know, these Apothecan drugs were subject to special offer prices that did not apply to BMS oncology drugs. (Kaszuba Dep. Tr. 210-12, annexed to Tretter Decl. as Exh. 1.) None of the drugs at issue in this case had special offer prices. (Id.)

In addition, plaintiffs often misconstrue the documents on which they rely. For example, plaintiffs cite a series of emails between Barbara Davidson and Stephen Pond as examples of “spread marketing”. (Plaintiffs’ Opp. at 20 and n. 23.) What the emails say is that a customer had concluded, based on information provided by Documetics, a third party vendor, that it was losing money on BMS’s Paraplatin and could make money on generic cisplatin, so it was buying cisplatin from a manufacturer other than BMS even though Paraplatin was better for patients. (PX 56 at 8116.) Far from marketing the spread, these emails demonstrate that BMS was losing sales on Paraplatin because it had no spread.

Plaintiffs also go to great lengths to create issues where none exist. For example, quoting Dr. Hartman, plaintiffs assert that BMS’s argument that it paid no attention to AWP’s is

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<sup>9</sup> In Plaintiffs’ Memorandum in Opposition to Track I Defendants’ Joint Motion for Summary Judgment (Pltfs.’ Joint Opp.), plaintiffs assert that “[d]efendants offer no specific definition, and they make no attempt to explain how they determined the AWP’s that they reported (Pltfs.’ Joint Opp. at 9.) BMS explains in detail how its list prices are calculated, and these documents explain that AWP was traditionally the wholesaler’s list price to retailers. This is consistent with the way the Congressional Budget Office defines AWP. (Supplemental Declaration of Steven M. Edwards, dated April 28, 2006 (“Supp. Edwards Decl.”) Exh. D at 4.)



implausible. (Pltfs.' Opp. at 13.) BMS does not make that argument. It paid attention to AWP's, but that does not make it liable. Similarly, plaintiffs contend that BMS understood that customers were interested in reimbursements. (*Id.* at 17.) BMS does not dispute that; but how is BMS's understanding deceptive or unfair?

Significantly, plaintiffs do not raise any genuine issue with respect to the analysis of Dr. Gregory K. Bell that, for all of the drugs at issue in this case, BMS had significant sales within 5% of its list price. (Bell Decl. ¶ 6 and Exhs. D and E.) Rather, plaintiffs embrace Dr. Bell's theory as consistent with their analysis (Pltfs.' Opp. at 14, 24-25), while at the same time attacking Dr. Bell as "an active participant in the fraud challenged here" (*id.* at 22).<sup>10</sup> Dr. Bell responds to these completely misleading attacks in a separate declaration (Supplemental Declaration of Gregory K. Bell, Ph.D., dated April 28, 2006), but at the end of the day they are completely irrelevant: Plaintiffs have not raised any genuine issue with respect to the substance of Dr. Bell's analysis.<sup>11</sup>

### Argument

#### I. BMS'S LIST PRICES WERE NEITHER DECEPTIVE NOR UNFAIR.

Plaintiffs contend that BMS's list prices violated Mass. G.L. ch. 93A because BMS did not periodically adjust them to reflect discounts. Thus, plaintiffs complain that BMS "did not use list prices to cause the reporting of lower AWP's when it offered mega price cuts on its products." (Pltfs.' Opp. at 13-14.) Plaintiffs accuse BMS of offering "[c]onfidential discounts, which were purposely not reflected in BMS's WLP's" (*id.* at 14), and they state that

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<sup>10</sup> Plaintiffs also quibble with various aspects of Dr. Bell's report, which were included so that he can testify about them in the event that there is a trial. (*See* Pltfs.' Opp. at 25.) BMS does not rely on those points in its motion for summary judgment.

<sup>11</sup> In their Rule 56.1 statement, plaintiffs complain that they have not had an opportunity to depose Dr. Bell. BMS has offered to make Dr. Bell available, but plaintiffs have not availed themselves of that opportunity. (Supp. Edwards Decl. ¶ 3.) Furthermore, Dr. Bell's analysis of the relationship between list prices and transaction prices is based on data that is equally available to plaintiffs.

none of the defendants “took any action to disclose their confidential pricing” (Pltfs.’ Joint Opp. at 11). (Emphasis omitted.)

Plaintiffs do not cite any cases which support their claim that list prices must be adjusted to reflect discounts. Furthermore, rather than distinguishing the cases cited by BMS,<sup>12</sup> plaintiffs fall back on Lupron and other cases which stand for the unexceptional proposition that, where a person utters a half truth or makes an affirmative misrepresentation, that person may have a duty to disclose additional information, including discounts. (Pltfs.’ Opp. at 6-7, 9-11.) All of those cases are inapposite because BMS’s list prices were neither half truths or affirmative misrepresentations -- they were exactly what they purported to be.

In addition to their failure to come up with any legal support for their position, plaintiffs completely ignore the basic economic principles articulated by Dr. Bell -- where, as here, a substantial number of customers are willing to pay the list price, it would not make economic sense for BMS to reduce its list price. Put another way, even though average prices to customers on the whole may be going down, if there are still some customers who are willing to pay list price, then lowering list price would cause BMS to lose its highest revenue – generating sales. (Bell Decl. ¶ 25.) To quote Dr. Bell: “such action would not be economically rational.” (Id.)

Plaintiffs criticize Dr. Bell’s conclusion, without dealing with his analysis, by pointing out that rational economic behavior does not justify price fixing, age discrimination or

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<sup>12</sup> Alves v. Harvard Pilgrim Health Care, Inc., 204 F. Supp. 2d 198 (D. Mass 2002), aff’d, 316 F.2d 290 (1st Cir. 2003); Bonilla v. Volvo Car Corp., 150 F.3d 62, 69-70 (1st Cir. 1998), cert. denied, 526 U.S. 1098 (1999); Langford v. Rite Aid of Alabama, Inc., 231 F.3d 1308 (11th Cir. 2000); Katzman v. Victoria’ Secret Catalogue, 167 F.R.D. 649, 656 (S.D.N.Y. 1996), aff’d, 113 F.3d 1229 (2d Cir. 1997).

the conduct as to which TAP pled guilty. (Pltfs.' Opp. at 23.)<sup>13</sup> BMS is not suggesting that rational economic behavior is a justification for per se violations of the law. BMS is simply pointing out that there is no per se rule requiring that list prices reflect discounts, and there are legitimate, non-fraudulent reasons why a seller would not adjust list prices to reflect discounts. See United Cooperative Farms, Inc. v. Citizens Bank, 2004 WL 829560 at \*1 (Mass. App. Ct. Apr. 16, 2004) ("Here the facts do not permit a reasonable inference that the bank acted with improper motives").<sup>14</sup>

Plaintiffs rely on Dr. Hartman's expert report to contend that the marketplace expected that the relationship between AWP and ASP would not exceed 30%. (Pltfs.' Opp. at 14.) As pointed out in the reports of defendants' experts,<sup>15</sup> and revealed by plaintiffs' inability to direct the Court to any particular portion of Dr. Hartman's report, Dr. Hartman's conclusion with respect to marketplace "expectations" is totally devoid of factual support. An expert conclusion, unsupported by any facts, is insufficient to raise a genuine issue that would defeat summary judgment. See, e.g., Hayes v. Douglas Dynamics, Inc., 8 F.3d 88, 92 (1st Cir. 1993); Merit Motors, Inc. v. Chrysler Corp., 569 F.2d 666, 672-73 (D.C. Cir. 1977); Johnson v. Brown & Williamson Tobacco Corp., 345 F. Supp. 2d 16, 20-21 (D. Mass. 2004).<sup>16</sup>

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<sup>13</sup> In continually invoking TAP, plaintiffs fail to point out that TAP pled guilty to violating the Prescription Drug Marketing Act ("PDMA"), which prohibits companies from encouraging physicians to bill Medicare for free samples, not the alleged AWP scheme. Plaintiffs have not asserted any claims under the PDMA.

<sup>14</sup> See also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 588 (1981) (summary judgment for defendants where price discounts were consistent with legitimate conduct).

<sup>15</sup> The Declarations of Gregory K. Bell, Eric M. Gaier, Linda A. Haegle, Daniel L. McFadden and Fiona Scott-Morton are annexed to the Supp. Edwards Decl. as Exhs F-J. We do not believe it is necessary for the Court to consider the merits of Dr. Hartman's reports because it does not proffer facts, as opposed to conclusions, that would controvert the facts supporting BMS's motion. If the Court is inclined to consider the merits of Dr. Hartman's reports, however, we are making defendants' expert reports available in the event that the Court wishes to consider them.

<sup>16</sup> It is also noteworthy that Dr. Hartman expresses no opinion concerning the marketplace's "expectations" with respect to BMS's list prices.

Plaintiffs also assert that “BMS admits to creating that ‘marketplace expectation’” (Pltfs.’ Opp. at 16), but they do not cite to any document, testimony or other evidence to support that extraordinary statement. That is because it is not true. BMS did not have any direct contact with Medicare or other payors concerning the prices of physician-administered drugs, and plaintiffs cannot fairly allege that it did.

Finally, plaintiffs suggest that a court cannot grant a motion for summary judgment where an issue of material fact exists as a result of conflicting expert testimony. (Pltfs.’ Opp. at 25-26.) That may be true where there is conflicting expert testimony with respect to material facts. Where, as here, the movant has proffered an expert analysis establishing certain facts -- i.e. that BMS had significant sales within 5% of list price -- and the non-movant does not challenge those facts but rather provides an expert report with unsupported conclusions on other issues, summary judgment is appropriate. United States v. 294 Various Gambling Devices, 718 F. Supp. 1236, 1241-42 (W.D. Pa. 1989).

## II. BMS DID NOT ENGAGE IN UNFAIR OR DECEPTIVE ACTS BY SUBMITTING ITS LIST PRICES TO THE PUBLICATIONS.

If, as demonstrated above, BMS’s list prices are not unfair or deceptive, the question becomes whether submitting them to the publications was an unfair or deceptive act. Plaintiffs contend that it was unfair or deceptive for BMS to do this because BMS knew that the publications would convert its list prices into allegedly fictitious AWP. (Pltfs.’ Opp. at 1.) The simple answer to that is that both the government and plaintiffs’ expert have admitted that Medicare was not defrauded by a mark-up of 20% to 25%.<sup>17</sup>

Even if the government had not known of the mark up of list prices to AWP, however, BMS cannot be held legally responsible for it because BMS did not publicly endorse

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<sup>17</sup> Gov’t Mem. in United States v. MacKenzie, at 1; Hartman Dep. Tr. 677-86, annexed to Edwards Decl. as Exhs. I and J.

the AWP's or control the actions of the publications. While it is true, as plaintiffs appear to suggest, that an intervening cause only breaks the causal connection when it is unforeseeable,<sup>18</sup> that standard only applies when the initial act is wrongful in some way. "The defendant is not liable merely because he could foresee the harm; the harm must be the kind that he should have avoided by acting more carefully." D. Dobbs, The Law of Torts at 447 (2001).

This concept is sometimes expressed in terms of duty. Under Mass. G.L. ch. 93A, a defendant in a commercial context generally does not have a duty to a plaintiff in the absence of a "contractual or business relationship." Nei v. Boston Survey Consultants, Inc., 388 Mass. 320, 324-25, 446 N.E.2d. 681, 684 (1983); see also Mitzan v. Medview Servs., Inc., 1999 WL 33105613 at \*9 (Mass. Super. June 16, 1999). "[T]he Supreme Judicial Court has stressed the existence of some contractual or business relationship between the parties as a precursor to liability under Chapter 93A." John Boyd Co. v. Boston Gas Co., 775 F. Supp. 435, 440 (D. Mass. 1991). "[A] plaintiff must allege some sort of transaction between the parties for liability to attach under [Mass. G.L. ch. 93A]." L.B. Corp. v. Schweitzer-Mauduit Int'l Inc., 121 F. Supp. 2d 147, 152 (D. Mass. 2000).

Here, there is no contractual or business relationship between BMS and plaintiffs. BMS submits list prices to publications who convert them to AWP's which are then used by Medicare to determine reimbursement rates for (and plaintiffs' co-payments to) doctors, who have a contractual or business relationship with plaintiffs. Under these circumstances, a person who has not engaged in wrongful conduct can only be liable for the conduct of a third party if that person controls the conduct of the third party or publicly endorses the third party's misstatements as its own. See In re Cabletron Sys., Inc., 311 F.3d 11, 38 (1st Cir. 2002).

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<sup>18</sup> See United States v. Park-Davis, 2003 WL 22048255 at \*5 (D. Mass. 2003).

As noted above, the witnesses, the documents and the language in BMS's publications that list prices do not include discounts all demonstrate that BMS does not control the way the publications go about calculating AWP's. Plaintiffs dismiss the disclaimers in BMS's communications with publications as "inadequate" (Pltfs.' Opp. at 16 n. 20), but what would plaintiffs have BMS do? Stop sending information to the publications and go out of business? The standard suggested by plaintiffs is one that no person could meet.<sup>19</sup>

### III. "MARKETING THE SPREAD," AS PLAINTIFFS DEFINE IT, DOES NOT VIOLATE THE LAW.

In response to BMS's suggestion that it is unclear what plaintiffs mean when they accuse BMS of "marketing the spread," plaintiffs make clear that they mean "actively discuss[ing] spreads with customers." (Pltfs.' Opp. at 17.) What plaintiffs do not make clear is how that violates the law. Plaintiffs do not claim that any discussions of spreads are deceptive; nor do they claim that BMS has such discussions with members of the class.

Plaintiffs cite the OIG guidance in support of their claim, but as we have pointed out before, the OIG guidance simply states that "manipulation" of the spread (which BMS does not do)<sup>20</sup> in "conjunction" with marketing the spread is strong evidence of the unlawful intent necessary to trigger the federal kickback statute (which is not involved in this case). 68 Fed. Reg. at 23737. Plaintiffs assert that the federal kickback statute is implicated because a violation of federal law would also be unfair and deceptive under state consumer protection acts. (Pltfs.' Opp. at 20 n. 24.) As the OIG guidance makes clear, however, the federal statute is complex,

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<sup>19</sup> Even if BMS had sent ASPs to the publications, it would not have made a difference. That much is made clear by the fact that, even though ASPs are now publicly available, the publications continue to publish AWP's by marking up list prices, and payors continue to reimburse physicians based on AWP's. (Supp. Edwards Decl. ¶ 6.)

<sup>20</sup> The OIG guidance describes manipulation as increasing the AWP, as opposed offering bona fide discounts that transfer remuneration from a seller to a buyer. 68 Fed. Reg. 23731, 23737 (May 5, 2003).

and it includes numerous safe harbors -- including a discount safe harbor -- none of which plaintiffs have addressed. See 68 Fed. Reg. at 23735 (discussing 42 U.S.C. § 1320a-7(b)(3)(A)).

Plaintiffs describe as “nonsense” BMS’s argument that, even it were guilty of marketing the spread, there is no causal relationship between such conduct and the prices they paid, but plaintiffs go on to say that “[w]hat matters” is that “BMS did not cause AWP’s to decrease commensurately with dramatic actual-sales-price reduction that were made in the interest of BMS’s bottom line.” (Pltfs.’ Opp. at 21.) This simply demonstrates BMS’s point. At bottom, plaintiffs are complaining about BMS’s failure to adjust list prices to reflect discounts; “marketing the spread” adds nothing to plaintiffs’ case.

#### IV. MEDICARE COULD NOT HAVE BEEN DECEIVED.

We agree with plaintiffs’ contention that, in our opening brief, we miscalculated the spreads for Cytosan and Rubex in the 1992 OIG report. (Pltfs.’ Opp. at 26.)<sup>21</sup> However, the spread properly calculated -- 143% -- vastly exceeds Dr. Hartman’s 30% yardstick and is consistent with the spreads that he found.<sup>22</sup> Plaintiffs dismiss this evidence on the ground that the 1992 OIG study is “just one *very limited* peek very early in the class period” (*id.*), but they fail to point out that this is one of the two surveys that Dr. Hartman relies on in calculating his 30% yardstick. (Berman Decl. Exh. 1 at ¶ 22(b).)

Plaintiffs assert that “because those drugs were multi-source, they were not included in Dr. Hartman’s yardsticks.” (Pltfs.’ Opp. at 27.) In other words, in calculating his 30% “yardstick” for Medicare’s expectations, Dr. Hartman: (1) relies on the spread for single-source brands, which did not exceed 30%; (2) ignores the spreads of which Medicare was aware

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<sup>21</sup>The 400% spread applies to another drug, Methotrexate Sodium.

<sup>22</sup> Dr. Hartman did not calculate any spreads above 108.4% for Cytosan in 1993, the first year for which he calculates spreads, and while the spreads for Rubex in 1994 -- the first year for which he calculates spreads for that drug -- varied considerably, they averaged 130%. See Edwards Decl. Exh. A.

for multi-source drugs, which range from 143% to 400%; and then (3) concludes that Medicare had an “expectation” that the spread for multi-source drugs would not exceed 30%. This demonstrates how ridiculous Dr. Hartman’s theory is.

Plaintiffs object to the October 1996 letter from Ven-A-Care to the head of HCFA, which depicts spreads for Vepesid in excess of 700%, on the ground that it is “objectionable hearsay.” (Pltfs.’ Opp. at 27.) The hearsay rule does not apply because the document is not being offered for the truth; it is being offered to demonstrate that HCFA was on notice of “megaspreads.” Gutierrez-Rodriguez v. Cartagena, 882 F.2d 553, 575 (1st Cir. 1989). In any event, the document is clearly admissible under Fed. R. Evid. 807 because it was a report to a federal agency, on Ven-A-Care letterhead, that was then produced by the agency in discovery and therefore has circumstantial guarantees of trustworthiness.<sup>23</sup>

#### V. THE AARONSONS DO NOT HAVE A CLAIM.

Plaintiffs concede that “plaintiffs like the Aaronsons must show that a defendant’s conduct proximately caused their actual injury” (Pltfs.’ Opp. at 28), but they argue that the Court cannot grant summary judgment on causation grounds because “this issue ultimately must be decided by the jury.” (Pltfs.’ Opp. at 29, citing Ellis v. Smith-Broadhurst, Inc., 268 S.E.2d 271, 273-74 (1981). There are numerous cases under the North Carolina unfair and deceptive practices act decided after Ellis, however, in which courts have granted summary judgment where plaintiffs have failed to show causation. See, e.g., Bartolomeo v. S.B. Thomas, Inc., 889 F.2d 530, 535 (4th Cir. 1989) (citing Ellis).

In addition, newly-discovered evidence obtained by BMS after it filed its moving brief demonstrates that the Aaronsons did not make payment for BMS-subject drugs based on

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<sup>23</sup> Plaintiffs also complain that the document is incomplete because the exhibits are missing. The exhibits are in the possession of counsel for Ven-A-Care, who is also a plaintiff in this MDL, who refuses to produce them. BMS has sought an order requiring their production. Judge Bowler has scheduled a hearing for May 9, 2006.



AWP. While plaintiffs claim that Presbyterian Hospital of North Carolina charged Mrs. Aaronson \$1,792.25 for a carboplatin treatment on August 10, 2004 (Pltfs.' Opp. at 27-28, n. 27) the Declaration of Michael D. Gum, dated March 23, 2006 ("Gum Decl.") demonstrates that the Hospital's charges for Mrs. Aaronson's treatment were not based on AWP. (Gum Decl. ¶¶ 5, 6.)<sup>24</sup> Mr. Gum is the Director of Pharmacy at Presbyterian Hospital and is knowledgeable "regarding the manner in which [the Hospital] bills patients for in-patient and out-patient medical services, including the methods by which the hospital determines charges for medications administered to patients." (Id. at ¶¶ 1-2.)

Furthermore, the Aaronsons made no payments for BMS drugs in August 2004. Medicare actually paid 100% of the Hospital's charges for Mrs. Aaronson's carboplatin treatments on August 10 and August 31, 2004.<sup>25</sup> (AARON 0100.) As the documents concerning those charges indicate, "this charge has been paid in full by Medicare. Therefore, no further payment will be made." (Id.)<sup>26</sup>

## VI. PLAINTIFFS HAVE NOT DEMONSTRATED HOW THEY CAN TRY THIS CASE.

Plaintiffs repeatedly assert that BMS has failed to prove that the government knew about all spreads on all drugs at all times. It is not necessary for the government to have perfect information in order to preclude the possibility of deception, but in any event plaintiffs have it backwards. The burden is on plaintiffs to demonstrate that the government was deceived.

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<sup>24</sup> Following up on the Court's invitation at the January 2006 class certification hearing to further investigate the facts regarding class representatives' payments based on AWP, BMS served a subpoena on Presbyterian Hospital in Charlotte, NC, Mrs. Aaronson's provider. In lieu of producing further documentation, the Hospital provided Mr. Gum's Declaration, which BMS's counsel received on March 23, 2006, too late to rely upon it in its moving summary judgment papers. Plaintiffs' counsel were provided with the Gum Declaration on March 30, 2006. (Supp. Edwards Decl. ¶ 4.)

<sup>25</sup> On August 10 and 31, Mrs. Aaronson was administered carboplatin, cisplatin and paclitaxel for a total charge of \$2,648.85 and Medicare paid the Hospital's entire charge for both treatments. (AARON 0016-17, 0100.)

<sup>26</sup> The co-payment made by Mrs. Aaronson for August 2004 of \$207.76 relates not to carboplatin, but to an injection for pegfilgrastim, which is not a BMS subject drug. (See AARON 0016 and 0100.)

Plaintiffs have utterly failed to carry that burden. They have not identified any witness who will testify or any document that will show that the government was deceived. If the Court denies this motion, it is difficult to imagine what plaintiffs' proof will be -- other than testimony by class members that they took the drug, made the co-payment and otherwise had no involvement in the transactions at issue (assuming plaintiffs can find a witness to provide that testimony, which they have not succeeded in doing to date), and Dr. Hartman, who is in no position to testify about what the government knew.

Conclusion

For all the foregoing reasons, BMS's motion for summary judgment should be granted.

Dated: Boston, Massachusetts  
April 28, 2006

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I, Lyndon M. Tretter, hereby certify that on April 28, 2006, pursuant to Paragraph 11 of Case Management Order No. 2, I have caused to be served on all counsel of record a true and correct copy of the foregoing BMS Defendants' Reply Memorandum of Law in Support of Their Motion for Summary Judgment, Supplemental Declaration of Steven M. Edwards, BMS's and OTN's Response to Plaintiffs' Local Rule 56.1 Counter-Statement, Supplemental Declaration of Gregory K. Bell, Ph.D. and Declaration of Michael O. Gum, by electronic service, by sending a copy of same to Lexis/Nexis File and Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter

Lyndon M. Tretter